WORKPLACE MANAGED CARE MULTISITE EVALUATION DESIGN

Prepared by

The Workplace Managed Care Cross-Site Evaluation Team

William Schlenger, Ph.D.
Georgia Karuntzos, MS.I.R.
Jeremy Bray, M.A.
Christopher Ringwalt, Dr. Ph.H.

Prepared under funding from
The Center for Substance Abuse Prevention

For the
Workplace Managed Care Steering Committee

Contact:
Georgia Karuntzos, M.S.I.R.
Research Triangle Institute
P.O. Box 12194
Research Triangle Park, NC 27709
(919) 541--6159
(919) 541-5945 (FAX)
gtk@rti.org (E-Mail)

April, 1999

Workplace Managed Care Multisite Evaluation Design

August, 1998 (appendices revised March 1999)

I. Introduction

One of the first questions that arises in multisite collaborations is: what's the cross-site evaluation design? The term "cross-site design" may evoke for many an image of a single design, implemented in uniform fashion at multiple sites, aimed at answering a limited and specific set of research questions. The strength of such unitary designs is that they provide definitive answers to relatively narrow questions.

The Workplace Managed Care (WMC) Program, on the other hand, was purposefully designed to be a multiprotocol, multipopulation effort that will generate knowledge--albeit less definitive than would result from a single protocol study--about a variety of WMC interventions and how they function within a variety of populations and contexts. The point of such studies is to capture diversity in interventions and populations, with the trade-off being that the knowledge generated, though broader, is less definitive. We think this trade-off is fully appropriate for the WMC Program, given the current state of the workplace managed care field. That is, at this stage of the development of the field there is a clear need to develop a broad understanding of the nature and scope of workplace managed care prevention efforts in general, which can provide an empirical basis for subsequent, more definitive, studies of specific interventions.

One of the most important challenges of multisite collaboratives in which each site implements a different intervention, serves a (somewhat) different population, etc., is to determine how best to weave the set of independently-designed demonstration projects into a cross-site study that adds value to the individual site studies. For the cross-site study of the WMC Program, we want a cross-site study that. For the : (a) generates knowledge that addresses the Program's objectives, and (b) takes optimal advantage of the potential strengths of multisite studies with respect to internal and external validity, enhanced power, etc.

Table 1 provides a summary of the currently planned intervention strategies and research designs proposed by each of the nine sites in the WMC Program. As one would expect, the sites vary along many important dimensions relevant to the cross-site evaluation, including the nature of the intervention (e.g., wellness programs, drug testing, EAP/EFAP), research design (e.g., non-equivalent comparison groups vs time-series), workplace characteristics, etc. This diversity is compounded by the fact that local circumstances (and therefore local plans) often change over time, as does the thinking of project teams, etc., and so each local project evolves in terms of its intervention and research design during the early months of the program. As a result, multisite collaboratives like the WMC Program typically begin with a "rubber ruler" phase, during which it may seem that plans and strategies are in continuous flux.

Although this flux is both useful and necessary, it is important to manage it such that the WMC Program moves forward in the desired direction--i.e., toward creating the strongest evidence feasible concerning substance abuse prevention and early intervention programs in the context of workplace managed care. To do so, we want (a) to stimulate the development of the strongest designs at each of the sites, and (b) to take advantage of opportunities to build in common elements across multiple sites in interventions, populations, etc., to enhance our ability to combine findings across sites, and thereby increase confidence in the findings. Doing so will increase the external validity of the findings and increase our ability to attribute any observed differences to the WMC interventions.

II. Methodology

So, *what is the WMC Program's cross-site design*? The answer is that the "design" ultimately will represent a weave of information provided by each of the study sites to address the Program's main questions, and the weave is likely to vary from question to question (since the individual site studies do not necessarily address every one of the Program's major questions). For a single protocol study, the cross-site design is a specific design that is implemented uniformly at each of the sites, and allows the analyst to pool the data across sites to conduct the cross-site analysis (using models that include "site" as a variable). For a multiprotocol, multipopulation study, the fact that the sites vary in their research designs and protocols (intervention strategies) complicates the cross-site design. With this type of study, the cross-site design takes into consideration the different research designs and intervention strategies across the study sites, and "combines" sites with common designs and common interventions to conduct the cross-site analysis and report the research findings. Data are "pooled" across sites only where commonalities in design, interventions, and populations allow. At present, however, we are making the conservative assumption that the opportunities to pool respondents across sites for analysis will likely be limited.

Instead of pooling the *data*, the primary strategy for adding value in multiprotocol studies involves pooling *findings* over sites. The analytic findings with respect to prevention/early intervention strategies could therefore be arrayed by type of design (e.g., non-equivalent comparison group or time-series) and by site, for the multiple outcomes of the study. Returning to our earlier terminology, this will allow us to "weave" the findings together--e.g., "In all four non-equivalent site level comparisons and three time series comparisons, individuals participating in substance abuse prevention/early intervention averaged significantly fewer injuries on the job in the follow-up period than those not participating ...". Table 2 shows an example of how our findings may be presented.

Based on this discussion, we can see that the individual site designs are the threads of the weave, and as a result the cross-site design is a consequence of the site designs, not vice-versa. Therefore, the cross-site design cannot be "finalized" until all of the individual site designs are clarified and actually implemented.

As the cross-site design is being finalized, however, a related challenge is to identify the common data elements that will be collected across the study sites to build a 'core data set' of information that can answer the Program's main questions. For the WMC Program, the 'core data set' will include: (a) *records based data* collected at the workplace (e.g., human resource records) and through managed care providers (e.g., health care utilization records, 'hot-line' records, EAP records) that provide information regarding the characteristics of the individuals served by the Program and the outcomes associated with involvement and/or exposure to the prevention/early intervention strategies; (b) *workplace survey data* collected prospectively from employees and their families that help us understand the relationship of the prevention/early intervention strategies to substance abuse attitudes and behaviors; and (c) *qualitative data* about program implementation that will be collected at each site under a common protocol to describe the prevention/early intervention strategies and the key elements required for implementing and sustaining these strategies at the workplace. Collectively these data sources provide the primary information base to answer the questions that the Program was created to answer.

At present, the Coordinating Center team is working with the sites on a variety of site-specific design issues and are in the process of making final recommendations and adjustments to address these issues. We have also reached consensus with the Steering Committee on the common elements of the 'core data set' to answer many of the Program's main questions. Appendix A provides the specific elements agreed upon, to date. The rationale used by the Steering Committee to select the core measures included (a) data elements that are meaningful to the interventions implemented across all nine study sites; (b) the availability and quality of data elements from all study sites; (c) CSAP's priority for answering the Program's study questions. The common qualitative/process data protocol has not yet been finalized, but Appendix B provides some initial thoughts by the Coordinating Center team on what it should contain.

Given the variation across sites in research designs, intervention strategies, and logistical constraints, not all nine site studies will address all of the Program's main questions. For this reason, we have categorized the research questions and related outcome measures for the WMC Program as 'core' measures and 'cluster' measures. Core measures address questions that can be uniformly answered by *all nine* site studies, and cluster measures address questions that can be answered by *subsets* of the nine site studies. Both core and cluster findings will provide important information about the outcomes associated with the WMC prevention/early intervention strategies.

III. Cross-site Evaluation Hypotheses and Questions

Given this background, in the following sections we describe briefly our current thinking about the cross-site design, organized by the questions specified in the GFA and agreed upon by the Steering Committee. The research questions address three broad areas of inquiry: (1) how do prevention/early intervention programs relate to workplace and individual outcomes, (2) what factors influence the relationships (e.g., extent of implementation, intervention effectiveness, sociodemographic or other characteristics of participants), and (3) what is the cost and cost-

effectiveness of prevention/early intervention programs?

A. Question 1: Are there differences in outcomes for individuals participating in substance abuse prevention/early intervention programs?

This is the overarching question of the WMC Program: is participation in substance abuse prevention/early intervention programs associated with more favorable outcomes for employees and their families? The cross-site evaluation can be conceived of as multiple replications of the test of participation vs nonparticipation in prevention/early intervention programs, examined across multiple dimensions of outcome (from the core data set). Each of the outcome dimensions can be conceived of as defining a subquestion, which are listed below.

1a: Is participation in substance abuse prevention/early intervention programs associated with lower injury rates at the workplace?

Question 1a will examine the hypothesis that prevention/early intervention strategies reduce injury rates at the workplace. To test this hypothesis, each of the nine study sites will provide workplace records reporting the rates of OSHA 200/100 claims per quarter for the study period. Workplace injury is a key outcome measure for examining the effects of prevention/early intervention on *workplace behaviors* and will be reported as a core finding.

1b: Is participation in substance abuse prevention/early intervention programs associated with lower rates of unplanned absenteeism, turnover, disability claims, disciplinary problems, and performance problems at the workplace?

The workplace outcomes represented in question 1b will each be provided by differing subset of the nine study sites, and will therefore be reported as cluster findings. Again, cluster measures represent important outcomes, but they are not available for all sites. For the sites providing these data, we will test the hypothesis that prevention/early intervention strategies are associated with reduced problems in the workplace. As with all outcome measures, the analytic findings will be arrayed by type of design and type of intervention, and by site. Absenteeism will be reported as the rate of absenteeism within the workplace per quarter for the study period. Turnover will be reported as the rate of turnover within the workplace per quarter during the study period. Disability claims will be reported as the total number of claims paid and total dollar value of these claims per quarter during the study period. At present, it is unclear in what format disciplinary claims and performance rating will be collected for the study participants or how these measures will be reported.

1c: Is participation in substance abuse prevention/early intervention programs associated with reduced the prevalence of alcohol and drug use among employees and/or covered lives?

The hypothesis that prevention/early intervention programs are associated with reduced

prevalence of alcohol use will be tested in two ways: (i) using drug toxicology results from study sites that can provide these data, and (ii) for the cluster of study sites that are adopting the cross-site survey measures, the prevalence of substance use will be estimated using self-reports of alcohol and drug use. The self-report information will be collected using a worksite survey administered to employees in conjunction with other health related questions. We anticipate that the methods for administering the worksite surveys across the subset of participating sites will vary from face-to-face health appraisals to website-based questionnaires. The prevalence of substance use will be reported as the proportion of employees reporting lifetime, past year, and past month use of alcohol and other drugs. The complete set of survey items that will be used as part of the cross-site evaluation are included in Appendix C.

1d: Is participation in substance abuse prevention/early intervention programs associated with improved employee (and their families) mental and physical health?

To examine the relationship of prevention/early intervention programs to employees' and their families' mental health and physical well-being, each study site will provide individual-level health care utilization data indicating the utilization of urgent/emergent care, outpatient services, inpatient services, substance abuse services, and mental health services. Use of urgent/emergent care will be operationalized as the number of visits to free-standing urgent/emergent care facilities per participant per quarter during the study period. Similarly, outpatient services will be operationalized as number of visits to outpatient providers per participant per quarter, and inpatient services will be reported as number of admissions (per participant, per quarter) to inpatient facilities. Utilization of substance abuse services and mental health services will be reported as number of visits (for outpatient) or admissions (for inpatient/residential) per quarter associated with substance abuse or mental health conditions. The diagnostic codes that will be used by the sites to build the indicators of substance abuse and mental health services are available in Appendix A under the section labeled Health Care Utilization Measures. These ICD-9 codes are taken from a manuscript entitled "Defining Mental Health/Substance Abuse Claimants" prepared in 1997 by the MEDSTAT Group, Research Triangle Institute, and Brandeis University for the SAMHSA/CMHS Medicaid, Medicare, and Managed Care Analysis project. Health care utilization measures will be reported as 'core' outcomes of the WMC study.

1e: Is participation in substance abuse prevention/early intervention programs associated with employees' perception of risk associated with alcohol and drug use?

A fundamental hypothesized outcome of prevention/early intervention programs is heightened awareness of the risks associated with alcohol and drug use. To test the hypothesis that workplace prevention interventions are associated with increased employee perceptions of risks associated with substance use, we will rely on self-report data collected by the subset of sites administering a worksite survey. Findings will be presented as the proportion of employees who report 'no risk,' 'slight risk,' 'moderate risk,' and 'great risk' associated with a varying levels of

alcohol and drug use.

B. Question 2: Are the prevention/EI programs implemented at the sites actually being used by covered employees and their families?

Whereas the questions listed above in Section A address the relationship of prevention/early intervention strategies to employee, covered life, and workplace outcomes of interest, Question 2 is the first of several that examine a variety of potential intervening and confounding factors that may influence the outcome findings. For example, before we attributed an observed reduction in health care utilization on the part of the intervention group to the workplace prevention strategies, we would want evidence of the extent to which members of the intervention group actually participated in the various components of the prevention/early intervention program.

Thus to understand fully the relationship of prevention/early intervention to the outcomes of interest and to interpret our findings appropriately, we need evidence that these interventions were in fact implemented at each participating study site. To provide such evidence, we will rely on information from two sources: (1) employee self-reports of their awareness and use of, and satisfaction with, the prevention/early intervention program(s) offered at their workplace, and (2) program records of participation (where appropriate). In addition to an implementation check, this information serves as the most proximal outcome of the prevention/early intervention strategies. In essence, this information answers the important question: "If you build it, will they come?"

C. Question 3: What is the relative effectiveness of the varying types of Prevention/Early Intervention programs?

As noted earlier, multiprotocol, multipopulation studies include a variety of intervention strategies implemented across a variety of workplace settings. To examine the comparative outcomes associated with the various types of programs, we will array our findings in tables structured similarly to Table 2, but focusing on the Prevention/EI program comparisons (e.g., wellness program vs EAP). Again, multiple dimensions of outcome will be included for each type of intervention program. Because of the diversity of interventions across sites, however, any findings will be suggestive rather than definitive. Table 3 provides a brief description of the strategies that the WMC Program study sites plan to implement, and highlights the similarities across programs.

D. Question 4: What is the relative impact of specific components of the various Prevention/Early Intervention programs?

This question raises the "mediator" issue--e.g., is the observed difference between prevention/EI vs non-prevention/EI groups accounted for, at least in part, by variation in specific services received? The design to address this question is to assess the extent to which exposure

to (or participation in) the various "parts"of the intervention reduces the observed treatment vs control outcome difference. Any such comparisons will be controlled for selected sociodemographic characteristics (e.g., age, race/ethnicity) to enhance comparability.

E. Question 5: What individual characteristics are related to program effectiveness?

This question raises the "moderator" issue--e.g., is the intervention differentially effective for people with different characteristics? We can study this by testing the interaction of the characteristic (e.g., gender, race/ethnicity, primary drug of abuse) with treatment assignment (e.g., prevention/EI vs non-prevention/EI) at the various sites. This will produce tables analogous to Table 2 that show, for example, that prevention/EI was associated with better outcomes for younger vs older persons, African-Americans vs Hispanics, or whatever characteristic is being examined. The demographic variables included in the core dataset are age, sex, race/ethnicity, occupational title, tenure with the company, and union status. Education and income are also included as cluster variables that will be analyzed by a subset of sites. Again, however, we plan to analyze the data primarily by site, and weave the findings togther.

F. Question 6: What are the direct costs of the Prevention/Early Intervention Program?

Each participating site will conduct a study of the cost associated with implementing its intervention, using guidelines provided by the Coordinating Center and the Steering Committee's Financial Outcomes Subcommittee. These are appropriately viewed as nine case studies of substance abuse prevention/early intervention program cost, conducted using consistent methodology, and the cross-site analysis will weave the findings from the nine together as with the other Program findings.

Cost estimates can be presented in various forms depending on the type of intervention, available data, and workplace setting. A common approach is to report the total annual cost of a program (e.g., personnel time, facilities, equipment and miscellaneous supplies for developing and implementing the interventions), as well as costs associated with the participants of the program. A more versatile approach is to estimate the average annual costs of the program. An average cost estimate will provide financial information that is normalized to adjust for program size and/or "dose level/exposure" to the intervention. This adjustment factor will allow programs of different sizes to be compared and analyzed in a meaningful way.

When calculating average program costs, several alternative values can be used as the normalizing factor. One option is to calculate the average annual cost per eligible employee (i.e, all employees eligible to receive EAP or other managed care program). This method will return the smallest average cost estimate because it spreads the total program cost over all employees who are eligible to use the program, regardless if they ever received services. Another option is to calculate the average annual cost per employee served. This method will return a larger average cost estimate than the first because it only accounts for employees who received services.

G. Question 7: What is the cost-effectiveness of the Prevention/Early Intervention Program?

Cost-effectiveness analysis considers both program costs and outcomes by forming and comparing ratios of incremental cost and effectiveness. As a simple example, suppose we are interested in the cost of enhanced managed care services relative to the changes in employee absenteeism. The numerator of the cost-effectiveness ratio in this example would be the incremental cost of providing enhanced managed care services to all eligible employees (i.e, total managed care costs including the enhanced prevention component costs), and the denominator would be the change in days absent for the employees between the follow-up period and the baseline period (i.e, the incremental change in effectiveness). Dividing incremental costs by incremental effectiveness (e.g., avoided days absent) results in an estimate of the cost per unit outcome for the population.

Thus cross-site cost-effectiveness analyses will be dependent on the findings of the sites' cost studies and of their outcome studies. Cost-effectiveness analysis is appealing because it considers the possibility of improved outcomes in exchange for using more resources.

Cost-effectiveness information is most compelling, however, when based on experimental (rather than observational) evidence, which we are not likely to have. For this and other reasons, we view any cost effectiveness information that the WMC Program might produce as preliminary and suggestive, rather than definitive.

IV. Analysis Framework

As noted above, we view the cross-site analyst's task as one of *weaving together* the findings from the various sites, and we envision most of the analysis being conducted within sites. In this conceptualization, the primary value added by the cross-site analysis stems from 'replication' over sites with similar interventions, using common metrics.

The sites' research designs generally fall into one of two classes--nonequivalent comparison group designs, and interrupted time series designs. The analytic approaches for these two designs differ, and our plans for each type are described briefly in the following paragraphs.

First, the most common design among the sites is the *nonequivalent comparison group* design. In such designs the prevention/early intervention program is implemented, for example, at Plant A but not at Plant B, and the post-implementation outcomes for employees at the two plants are compared. The design's name derives from the fact that the characteristics at baseline of the workforces of the two plants--i.e., what we might think of as the plants' 'case mixes'--are by definition *not equivalent* at the beginning of the study. As a result, any differences that we observe in outcomes for employees at the two plants at follow-up could be due to the effects of the program, to the case-mix differences, or to both.

Traditionally, this problem has been addressed statistically, via the use of analysis of covariance, in which we test the difference in follow-up outcomes between the intervention and comparison groups, adjusting for levels of the outcome and other relevant characteristics of the populations *at baseline*. Thus, in this approach multivariate models are estimated that include baseline levels of employee characteristics that are believed to be related to the outcomes being studied. By controlling for these characteristics, the nonequivalent groups are made more equivalent, thus reducing--at least to some extent--the likelihood that observed outcome differences are due to 'case mix' differences at baseline. For example, if younger people are more likely than older to use drugs, then we would want to control for age in comparisons of drug use outcomes.

In recent years, however, more sophisticated approaches to this problem have been developed. These methods generally involve modeling the differences between the two groups, using the model to create a "predicted probability of getting the intervention," and incorporating that predicted probability into the outcome analyses to adjust for the bias. One such method that follows the logic developed by Rubin and Little is referred to as the 'propensity score' approach, and another developed by Heckman is referred to as the 'Heckman correction.'

Although we have not yet decided which of the approaches to implement, we plan to use one of these methods to adjust for group nonequivalence at baseline, and also to adjust for bias introduced by nonresponse at follow-up (the context in which Rubin and Little's work was originally developed). Thus, we envision the analyses to be conducted via multivariate models that adjust to the extent feasible for group nonequivalence and for nonresponse at follow-up. We recognize, however, that our ability to do so is substantially constrained by the limited number of characteristics that are included in the core data set.

Second, some of the sites have proposed interrupted time series designs to answer at least some of their research questions. For analyses of data from these sites, we will draw from the family of existing methods for analyzing time series data. Given that in time series designs each subject may be thought of as his/her own "control" over time, and that what one is looking for in time series designs is what may be thought of as differences between the groups in trend line slopes, the nonequivalence of groups at baseline is somewhat less troubling in this context.

V. Data Management

At present, the study teams at each site are in the process of coordinating efforts with the participating worksites and managed care organizations to finalize procedures for obtaining data from their various recordkeeping systems. The diversity in organizational size, complexity, union involvement, and relationships with key personnel will affect the ease and timing in which data can be obtained. We anticipate that all study worksites will have a test file of data ready to transfer to the WMC server by September of 1998. The goal of the Program is to have retrospective data from each site for analysis by November of 1998. Prospective data will flow on a quarterly basis

based on a schedule to be determined by the Steering Committee.

Before any data are transferred to the WMC server, all identifiers will be stripped from the files. The sites' study teams must confirm that no data transferred to the WMC server will be linkable to a specific individual. To assure this, each site will create and manage a 'link file' that includes a unique identifier for each study participant (e.g., social security number, employee ID) and a corresponding non-identifying study ID. The data files transferred to the server should include the non-identifying study ID. A Coordinating Center analyst will obtain the data from the WMC server and secure it in a dedicated password protected workstation. Only the assigned analyst will have password access to this system. When the data are not being used, they will be removed from the harddrive and kept on CD-ROM (or diskette) in a locked file cabinet.

Consistent with the publication guidelines agreed upon by the WMC Steering Committee, all data provided by the sites for the cross-site evaluation will be kept by RTI for at least 10 years beyond the end of the WMC project. RTI will not publish or disseminate in any way research findings associated with the WMC Program without prior approval of the WMC Steering Committee, but RTI may utilize the data to disseminate findings (in aggregate form and without identifying information) that further the Program's goals, within the WMC publication guidelines and in accordance with 42,CFR, Part 2. Appendix D expands on RTI's assurance of data confidentiality.

VI. Quality Control Mechanisms

Data quality control is a significant responsibility that is typically shared by sites and the Coordinating Center in multisite collaboratives. The data files that will be transferred to the (firewall protected) WMC server and used for cross-site analysis will be prepared and first checked for errors by the evaluation team at each of the study sites. Data quality checks will also be performed by the Coordinating Center once we have obtained the data from the WMC server.

Because the Coordinating Center does not manage the actual data elements and may not fully understand all of the details of the specific worksite information (e.g., workforce size, mean age, turnover rates, benefits levels, etc), the quality checks that we perform will be limited to logical range checks and comparisons between quarterly files. It is critical that the sites' study teams make certain that they are familiar with the data, have checked it thoroughly, and confirm that it is correct before transferring it to the WMC server. We recommend that the systems programmers who actually create the data sets (e.g., at the Human Resources Dept., at the managed care company) examine the data and compute descriptive statistics (e.g., means, standard deviations, frequency counts), and that the site's study team replicate these runs to confirm that the data have been successfully transferred.

Additionally, to ensure the quality of the WMC Program's data, we describe some common problems and provide some guidelines and recommendations in the following sections.

Data quality problems. Very few MCO's or health insurance organizations collect utilization data for research purposes. Instead, most maintain these data for accounting or billing purposes, and therefore may not maintain many of the kinds of variables that substantive analysts would like to have. Some MCO's simply code the occurrence of an encounter, without indication of the nature of the problem itself. Even where codes identifying the problem (ICD or CPT) are used, there may be serious validity questions. For example, an alcohol-related problem might be coded as acute gastritis, as depression, or as a sleep disorder depending on the presenting complaint and the sophistication of the practitioner. If an IV drug user is treated for hepatitis, the liver disease may get coded but not the drug use. Also, many physicians do not use ICD codes - the billing department only codes the *services* provided by the physician, not the condition(s) for which the services were provided. In a capitated system there typically is no billing department, and hence no codes. In some cases, diagnostic data may be available from patient charts; however, chart data have their own problems. Abstracting information from charts is time consuming, costly, and raises questions of reliability. Charting behavior can be variable within providers and varies widely between providers. Even with trained, skilled coders, accuracy and consistency may be a problem. Site study teams should examine all data fields for accuracy and consistency between fields, and also for missing data. Close contact with the MCO can help resolve data quality problems and detect fields with a large percentage of missing data early in the data collection process. Site study teams should be prepared to develop alternative analysis plans based on the actual availability of data.

Multiple data sources per patient. Some patients have multiple health insurance plans and many MCO's now offer 'point of service' plans that allow patients to use out-of-network providers. Both of these circumstances increase the likelihood that portions of a patient's total health care utilization will not be captured in any one database. This problem is even more troublesome when the patient population is defined based on a common employer. Multiple health plans offered by most employers make it almost certain that grantees will need to obtain data from multiple sources in order to completely characterize the health care utilization of a given population. An inherent problem with multiple data sources is inconsistency between sources. Site study teams should work closely with their MCO(s) to identify all relevant data sources and map data fields and variable definitions between sources to eliminate inconsistencies and inaccuracies.

Changes in patient enrollment status. When analyzing utilization data from insurer or MCO data bases, it is critical to document enrollment dates for each individual. This is important because individuals may change health plans or drop health coverage entirely during the course of a study. Information about enrollment status allows the analyst to distinguish between an enrolled individual who has no health care utilization in a given time period and an individual who was not enrolled during that time period. Both cases will show up in the health care utilization data as having no utilization, but these cases obviously have different implications. Site study teams should collect enrollment dates whenever possible to determine if a patient was eligible for services on a given day.

Problems with data collection/transfer. The actual process of collecting or transferring the data from the MCO or heath insurance organization can pose another set of problems to grantees. Health care utilization databases are often very large and costly to maintain. For this reason, many organizations will routinely archive or even erase large portions of their older utilization data. Site study teams should be aware of this possibility and work closely with the MCO or health insurance organization to insure that needed data are not accidentally lost due to unforeseen data archives or purges. Processing delays for individual level claims records can also present problems. The typical procedure for processing claims may take 2-3 weeks from the point of the encounter to the point of provider approval of the claim. In some cases this process may take longer if claims are disputed or an error has been made when filling out the claims forms. Site study teams should be aware of time lags in processing data when determining cut off points for data analysis.

Changes in the organization providing the data. Finally, site study teams should be mindful that the health care industry is undergoing a period of rapid change. MCOs are re-organizing their corporate structures and changing their data systems in the process. Employers are constantly looking for lower cost alternatives for health care, and this in turn exerts pressure on MCOs to change rapidly to stay competitive. In addition, MCO/provider reporting requirements are changing. This is due in part to the emerging Medicaid managed care market, but also related to a push toward greater provider accountability. Site study teams should take care to be aware of and document any changes in the organizations providing data that may change the availability of certain data fields or impact the utilization patterns of patients. To assure access to employee level data, site study teams should negotiate with and obtain written confirmation from the MCO that these data can and will be made available to them for research purposes.

In summary, the success of the multisite evaluation builds on (1) the successful implementation of each site's prevention/early intervention program, (2) strong site-level study designs, and (3) the availability of common data elements from each site to answer the questions noted above. As we have discussed, we expect to collect data from the sites on a minimum set of core domains gathered through a variety of data sources (i.e., workplace surveys, HR records, health claim records, EAP and other managed care program records). To gather meaningful data, we will work with the Steering Committee to operationalize each data element in terms of how it is defined (e.g., absenteeism defined as sick leave vs personal days off), how it is measured (e.g., daily vs monthly), and when it is collected (quarterly vs annually). We will also ask each site to pilot test the data transmission procedures to confirm that we can read and merge site level, prior to full scale data collection. Finally, we will ask each site to adhere to the established site-level and cross-site data collection protocols throughout the duration of the study, and to discuss with us potential modifications before they are implemented.

Table 1. Workplace Managed Care Program Research Design Summary by Site

WMC Program Research Design	G-7	G-2	G-3	G-6	G-4	G-1	G-9	G-5	G-8
Non-equivalent comparison group design; subject level matching for occupational categories across companies	X (IQ Health)								
Non-equivalent comparison group design; site level matching for sociodemographic characteristics within company		X (peer interven-tion)							
Non-equivalent comparison group design; site level matching for worksite characteristics across companies					X (preven-tion interven-tion)				
Non-equivalent comparison group design; site level comparisons within company			X (wellness plus SA Winston/ Burlngtn)	X (Gibson site inter-vention)	X (drug testing)	X (peer/Non-peer)			

Table 1. Workplace Managed Care Program Research Design Summary by Site

WMC Program Research Design	G-7	G-2	G-3	G-6	G-4	G-1	G-9	G-5	G-8
Non-equivalent comparison group design; subject level matching for occupational categories and sociodemographic characteristics within company									X (KP/ VBH)
Pre-post randomized experiment			X (retro NIDA study)						
Pre-post quasi experiment						X (spanish materials)			
Interrupted time-series within site		X (peer interven-tion)			X (drug testing + interven-tion)	X (peer units)			
Staggered interrupted time-series across worksites within company							X (interven-tion)		

Table 1. Workplace Managed Care Program Research Design Summary by Site

WMC Program Research Design	**G-7**	**G-2**	**G-3**	**G-6**	**G-4**	**G-1**	**G-9**	**G-5**	**G-8**
Equivalent comparison group design; stratified by department; random assignment of units to intervention and control								X (random assign to follow-up counselor)	

Table 2. Example of Array of Prevention/EI vs. Non-Prevention/EI Outcome Findings

		Outcome Domain			
Design	**Site**	**Substance Use on the Job**		**Perceived Risk of Alcohol and other Drugs**	
Non-Equivalent group design; site level comparisons within company		**Prevention/ Early Intervention**	**Non-Prevention/ Early Intervention**	**Prevention/ Early Intervention**	**Non-Prevention/ Early Intervention**
	Site 1	3.2	5.7	1.1	2.3
	Site 2	.	.	.	.
	Site 3	.	.	.	.
	Site 4	.	.	.	.
Interrupted Time-Series design; within site comparisons					
	Site 1	4.1	5.4	2.7	3.6
	Site 2	.	.	.	.

	Site 3	.	.	.	.

Table 3. Commonalities Across Program Types

Program Type	Intervention Strategies		Workforce Demographics		Research Design	
	Similarities	**Differences**	**Similarities**	**Differences**	**Similarities**	**Differences**
PEER TRAINING						
G-1 G-2	peer training in detection of SA problems and volunteers for peer counseling EAP/EFAP services offered at intervention and comparison sites	peer counseling is rarely used as part of the G-1 program; focus more on "mark off" for SA impairment Peer intervention to "assist possibly impaired employees" related to a variety of problems is a major goal for Weyhsr	Large (20k+) workforce Multisite Company Primarily male workforce Industrial setting Union setting Random drug testing	G-1 primarily Caucasian G-2 unclear Pre-employment drug testing for G-2	Non-equivalent comparison group design Site level comparisons within company Interrupted time-series within site	Comparison group selected by non-ORB status by G-1 Comparison group selected by demographic similarities by G-2
HEALTH PROMOTION MODEL						
Educational Materials						

Table 3. Commonalities Across Program Types

Program Type	Intervention Strategies		Workforce Demographics		Research Design	
	Similarities	**Differences**	**Similarities**	**Differences**	**Similarities**	**Differences**
G-1 G-3 G-4 G-5 G-6	Printed educational materials for employees and families Seminars G-4 and G-3 offer educational materials as part of enhanced EAP services G-1, G-5, and G-6 offer educational materials through company wellness program	New culturally sensitive Spanish materials for G-1 Programs in schools for G-1 Video Series for G-3	G-4, G-3 and G-6 are medium sized (1,000-4,000 employee) companies G-1 and G-4 are industrial settings with predominately Caucasian male employees G-4, G-6 and G-1 have random drug testing	G-1 is a large 20K+ multisite company G-6 and G-3 are professional settings with predominately Caucasian female employees G-6 and G-3 are non-union settings G-3 and G-5 have no drug testing	G-1, G-4, G-6, G-3: non-equivalent comparison group design with site level comparisons within company	G-5: equivalent comparison group design stratified by department with random assignment of departmental units to intervention and control
Health Fairs						
G-3 G-4 G-6 G-9	Health fairs for SA and general wellness G-9 and G-4 Health Fairs offered through EAP	Health fairs at G-6 part of Standard package and not considered an enhancement at the intervention site.	G-4 and G-9 multisite industrial settings and G-6 predominately female workforce and many professional staff	G-6 workforce includes medical staff	G-4, G-6, G-3: non-equivalent comparison group design with site level comparisons within company G-4 and G-9: time series design	G-9: Staggered time series design at annual implementation intervals at 3 worksites
Dial-A-Nurse Program						

Table 3. Commonalities Across Program Types

Program Type	Intervention Strategies		Workforce Demographics		Research Design	
	Similarities	**Differences**	**Similarities**	**Differences**	**Similarities**	**Differences**
G-4 G-8	Dial and 800 number and get routed to the appropriate on-line service Dial-a-nurse program part of a larger health promotion program Unclear if G-8 still has this program?	G-8's primary intervention is an interactive Web site program G-4's main intervention program(s) are drug testing levels and EAP based health promotion		G-4 multisite industrial setting G-8 University setting	G-4 and G-8: non-equivalent comparison group design	G-4: site level comparisons within company G-8: individual level comparisons by risk levels
Interactive On-line Workshop Series						
G-8	Intervention components unclear?					
Health Risk Appraisal						
Health Risk Appraisals G-7 G-5 G-6	HRA to identify potentially problematic drinkers Written feedback to individual Brief counseling or referral to counseling Outreach to PCP's	Referral training for worksite supervisors/ union reps/EAP providers for G-5 Mailed HRA for G-5, on sight for G-7 and G-6 Biometric Screening for G-5	G-7 and G-5 both University settings G-6 and G-7 both include EAP and drug testing services as part of wellness strategies G-5 and G-6 target workforce includes medical technical and administrative	G-7 includes professional administrative and maintenance, but excludes medical?	G-6 and G-7: non-equivalent comparison group design	G-5: equivalent comparison group design stratified by department with random assignment of departmental units to intervention and control G-6: site level comparisons within company G-7: individual level comparisons between IQ health and non-IQ health employees
Enhanced EAP/EFAP						

Table 3. Commonalities Across Program Types

Program Type	Intervention Strategies		Workforce Demographics		Research Design	
	Similarities	**Differences**	**Similarities**	**Differences**	**Similarities**	**Differences**
G-3 G-9 G-7 G-6 G-4	Manager/Supervisor Training in early SA detection Written materials for employees and families promoting SA prevention and benefits of EAP	G-7 and G-9 have for cause and re-entry drug testing through EAP; G-3 and G-6 do not G-3 has a video series as part of prevention program (G-4 considering this program?).	G-4 and G-9 multisite union industrial settings predominately Caucasian male G-3, G-7 and G-6 predominately female Caucasian workforce professional staff	G-7 is a university setting G-6 is a medical center G-3 is a professional office setting	G-6, G-7 G-4, G-3: non-equivalent comparison group design G-3, G-6, G-4: site level comparisons within company G-4 and G-9: time series design	G-7: Individual level comparisons between IQ health and non-IQ health employees G-9: Staggered time series design at annual implementation intervals at 3 worksites
Drug Testing						
G-4	Increased random testing of safety/information sensitive personnel					

APPENDIX A: Workplace Managed Care Program Core Dataset Measures
(3/25/99)

Table 1. Workplace HR Measures		
HR Measures	**CORE DATASET VARIABLES**	
Employee Identifiers	Study Identifier:	Provide a unique non-identifying number used to link individual-level data across data sets within site.
Intervening Variables	Study Group:	Designate Intervention (INT) or Comparison (CMP) Group assignment. If multiple levels of INT or CMP group are available, append a numeric to the INT or CMP assignment (e.g., INT1, INT2, INT3). If a study participant moves from a study group/site to a non-participating group/site, designate the study status as Ineligible (INELIG). Study group assignment may change between quarters. This assignment will be provided by the researcher.
	Year of birth:	Provide the year of birth as available in the HR system. If possible, provide a four-digit value (e.g., 1954)
	Sex:	Provide data as available in HR system. If possible avoid one letter fields (M/F or 1/0). 'Male' and 'Female' is preferred to avoid typographical errors.
	Race/ethnicity:	Provide data as available in HR system. Data will be collapsed by coordinating center across nine sites post fact.
	Job Type/Occupational Title:	Use the BLS Occupational Classification System MOGs. A-K. http://www.bls.gov/ocsm/commain.htm
	Health Plan Enrollment:	Designate HMO, PPO POS, FFS, or 'Not Enrolled' in a given quarter. In some cases, the type of plan may change within a quarter. Provide the plan status at the end of the quarter. If multiple plans of the same type are available, designate the specific plan with a numeric value appended to the type of plan (e.g., HMO1, HMO2, PPO1, PPO2).
	Job Tenure:	Number of years of service with the company in a given quarter. Caution: Internal transfers or status changes may affect how job tenure is tracked. Confirm that this variable reflects all years of service with the company.
	Union Status:	Designate Yes/No or Not Applicable. Union status is defined as "covered by a collective bargaining agreement". If worksite is non-union indicate 'not applicable' for all individuals at that worksite
	Termination Status:	Designate Yes/No for termination status per quarter. Termination status may change within a quarter. Please provide the status at the end of the quarter.
Outcome Variable	Injuries:	Number of OSHA 200/100 claims per quarter. Provide separate fields for OSHA 200 and 100, if possible.

HR Measures	**CLUSTER VARIABLES (Data only available at a subset of sites)**	
Intervening Variables	Education:	Provide data as available in HR system. As an example, data may be available as number of completed years of education, or highest degree obtained.

	Earnings:	Provide quarterly gross pay. Include bonuses, commissions, overtime, etc. If hourly or monthly wages are provided, add up to the quarter to create the variable. If annual wages are provided divide the wages by 4 for the quarter to create the variable.
Outcome Variables	Disability Claims:	Provide the total number of claims paid per quarter.
	Dollar Value of Disability Claims	Provide the total $$ value of claims paid per quarter.
	Absenteeism:	Number of days absent per quarter.
	Positive 'For Cause' Drug Test results:	Provide total positive 'for cause' drug test results per quarter.
	Negative 'For Cause' Drug Test results:	Provide total negative 'for cause' drug test results per quarter.

Table 2.	Health Care Utilization Measures	
	CORE DATASET VARIABLES	
	Study Identifier:	Non-Identifying number used to link individual-level data across data sets within site.
	Client Identifier:	Non-Identifying number linked to the patient.
	Subscriber Identifier:	Non-Identifying number that links the client to the subscriber.
	Year of birth:	Provide the client's year of birth as available in the MCO system. If possible, provide a four-digit value (e.g., 1954)
	Sex:	Provide data as available in MCO system. If possible avoid one letter fields (M/F or 1/0). 'Male and 'Female' is preferred to avoid typographical errors.
	Marital status:	Provide client data as available in MCO system.
	Relation to Subscriber	Designate subscriber, spouse, or dependent. Note: Each dependent should be assigned a unique patient identifier linked to the subscriber.
	Enrolled in Plan:	Designate HMO, PPO POS, FFS, or 'Not Enrolled' in a given quarter. In some cases, the type of plan may change within a quarter. Provide the plan status at the end of the quarter. If multiple plans of the same type are available, designate the specific plan with a numeric value appended to the type of plan (e.g., HMO1, HMO2, PPO1, PPO2).
Outcome Variables	ER Utilization WITH an Admission:	Number of total days in which an ER visit occurred with an admission per quarter.
	Cost of ER Utilization WITH an Admission:	Total costs associated with ER visits with an admission per quarter. The four cost categories are: (1) Charges: amount the provider bills the MCO (2) Patient out-of-pocket/Deductibles/Co-payment: amount the patient pays (3) Paid amount: amount payed by the insurance company to the provider (4) Allowed amount: maximum amount insurance company would pay the provider.
	ER Utilization with NO Admission:	Number of total days in which an ER visits occurred with NO admission per quarter.
	Cost of ER Utilization with NO Admission::	Total costs (charges, co-pay, paid amount, allowed amount) associated with ER visits with NO admission per quarter.
	Urgent/Emergent Care Utilization:	Number of total days in which a free-standing urgent/emergent care visit occurred per quarter.
	Cost of Urgent/Emergent Care Utilization:	Total costs (charges, co-pay, paid amount, allowed amount) associated with Urgent/Emergent Care visits per quarter.
	Outpatient Utilization:	Number of total days in which an outpatient visit occurred per quarter.
	Costs of Outpatient Utilization:	Total costs (charges, co-pay, paid amount, allowed amount) associated with outpatient visits per quarter.
	Inpatient Admissions:	Number of total admissions to an inpatient facility per quarter
	Inpatient Days:	Number of total days of stay in an inpatient facility per quarter.

Table 2.	Health Care Utilization Measures	
	CORE DATASET VARIABLES	
	Costs of Inpatient Stays:	Total costs (charges, co-pay, paid amount, allowed amount) associated with inpatient stays per quarter.
	Utilization related to Substance Abuse (and related medical conditions) or Utilization related to Mental Health conditions	Number of total days in which an ER visit (with no admission) occurred associated with substance abuse (and related medical conditions) or mental health per quarter — and,
		Number of total days in which an ER visit (with an admission) occurred associated with substance abuse (and related medical conditions) or mental health per quarter — and,
		Number of total days in which an Urgent/Emergent Care visit occurred associated with substance abuse(and related medical conditions) or mental health per quarter — and,
		Number of total days in which an Outpatient visit occurred associated with substance abuse(and related medical conditions) or mental health per quarter — and,
		Number of inpatient admissions associated with substance abuse (and related medical conditions) or mental health per quarter.
		Number of inpatient days of stay associated with substance abuse (and related medical conditions) or mental health per quarter.
	Costs related to Substance Abuse (and related medical conditions) or Utilization related to Mental Health conditions	Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and related medical conditions) or mental health ER visits (with NO admission) per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and related medical conditions) or mental health ER visits (WITH) an admission) per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and related medical conditions) or mental health Urgent/Emergent Care visits per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and related medical conditions) or mental health Outpatient visits per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and related medical conditions) or mental health Inpatient days of stay per quarter.
	Utilization related to Substance Abuse (and related medical conditions) and no mental health	Number of total days in which an ER visit (with no admission) occurred associated with substance abuse (and related medical conditions) and no mental health per quarter — and,
		Number of total days in which an ER visit (with an admission) occurred associated with substance abuse (and related medical conditions) and no mental health per quarter — and,
		Number of total days in which an Urgent/Emergent Care visit occurred associated with substance abuse (and related medical conditions) and no mental health per quarter — and,

Table 2. Health Care Utilization Measures		
	CORE DATASET VARIABLES	
		Number of total days in which an Outpatient visit occurred associated with substance abuse (and related medical conditions) and no mental health per quarter — and,
		Number of inpatient admissions associated with substance abuse (and related medical conditions) and no mental health per quarter.
		Number of total Inpatient days of stay associated with substance abuse (and related medical conditions) and no mental health per quarter — and,
	Costs related to Substance Abuse (and related medical conditions) and no mental health	Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and no mental health) ER visits (with no admission) per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and no mental health) ER visits (with an admission) per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and no mental health) Urgent/Emergent Care visits per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and no mental health) Outpatient visits per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with substance abuse (and no mental health) Inpatient days of stay per quarter.
	Utilization related to Mental Health conditions and no substance abuse	Number of total days in which an ER visit (with no admission) occurred associated with mental health and no substance abuse per quarter — and,
		Number of total days in which an ER visit (with an admission) occurred associated with mental health and no substance abuse per quarter — and,
		Number of total days in which an Urgent/Emergent Care visit occurred associated with mental health and no substance abuse per quarter — and,
		Number of total days in which an Outpatient visit occurred associated with mental health and no substance abuse per quarter — and,
		Number of inpatient admissions associated with mental health (and no substance abuse) per quarter --- and,
		Number of total Inpatient days of stay associated with mental health (and no substance abuse) per quarter.
	Costs related to Mental Health conditions and no substance abuse	Total costs (charges, co-pay, paid amount, allowed amount) associated with mental health (and no substance abuse) ER visits (with no admission) per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with mental health (and no substance abuse) ER visits (with an admission) per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with mental health (and no substance abuse) Urgent/Emergent Care visits per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with mental health (and no substance abuse) Outpatient visits per quarter.
		Total costs (charges, co-pay, paid amount, allowed amount) associated with mental health (and no substance abuse) Inpatient days of stay per quarter.

Table 3. MCO Information to *Create* Core Utilization and Cost Variables		
MCO Records	**SERVICE LEVEL DATA:**	
	Date of service or admission:	date the service was rendered at ER/Urgent Care/ Outpatient facility — or, date of admission to inpatient facility. The date is required to determine which quarter the service or admission occurred.
	Location of service:	designated as Emergency Room, Free Standing Urgent Care facility, Outpatient facility, or Inpatient facility to which a patient has been admitted. The location code is used to determine where the service occurred.
	Substance Abuse (and related medical conditions) ICD-9 diagnosis codes*:	ICD-9 codes indicating Substance Abuse (and related medical conditions)are: [291, 292, 303-305, 357.5, 357.6, 425.5, 535.3, 571.0-571.3, 571.5, 648.3, 655.4, 655.5, 760.7 (exclude 760.74 and 760.79) , 779.5, 790.3 962.0, 965.0, 967-970, 977.0, 977.3, 980, V70.4, V79.1]. Use Primary, secondary, or tertiary diagnosis to determine substance abuse or related medical condition.
	Mental Health ICD-9 diagnosis codes*:	ICD-9 codes indicating Mental Health are: [290, 293-302, 306-316, 331.0, 648.4]. Use Primary, secondary, or tertiary diagnosis to determine mental health diagnosis.

* ICD-9 codes to indicate Substance Use and Mental Health are taken from "Defining Mental Health/Substance Abuse Claimants" SAMHSA/CMHS Medicaid, Medicare, and Managed Care Analysis Project. Prepared by the MEDSTAT Group, Research Triangle Institute, and Brandeis University, 1997. Additional codes were added by recommendation of the Steering Committee. If ICD-9 codes are not available, coordinate with RTI to identify alternative classification schemes.

APPENDIX A (continued)

Workplace Survey Construct		
Survey Constructs*	**CORE DATASET CONSTRUCTS**	**CLUSTER CONSTRUCT**
Intervening Variables	Demographic Characteristics	
	Awareness of Prevention Program Components	Awareness of EAP Services
	Willing to use Prevention Program	Willingness to Use EAP Services
	Use of Prevention Program Components	Use of EAP Services
	Satisfaction with Prevention Program Components	Satisfaction with EAP Services
Outcome Variables	Substance abuse prevalence (AOD)	
	Perceptions of harm	

* Core Survey Constructs (and items) have been recommended, but have not been finalized and agreed upon by the Steering Committee

APPENDIX B

PROCESS EVALUATION

We have discussed the topic of "process evaluation" at several Steering Committee meetings, but have not made much progress in operationalizing plans for site-level or cross-site process measures. Now that the Measures Subcommittee has bitten the bullet, I thought it might be useful to provide some thoughts about what the role of process evaluation in the cross-site and what process information we anticipate needing to meet the cross-site study objectives.

A. Rationale and Conceptualization

A good place to start is by addressing the question: Why are we interested in studying the "process?" In thinking about this in the past, we have noted that the evaluation of programs like the WMC can be divided into process and outcome parts, respectively, by the following two general evaluation questions: (1) what did the grantees do [i.e., what were the interventions], and (2) what difference did it make? Under this conceptualization, the process evaluation focuses on describing the details of the sites' interventions and their underlying logic and on providing quantitative information related to "dose" [i.e., how much and what kind of intervention did participants in the "treatment" and "comparison" groups actually receive].

One important reason for including a thorough process evaluation as part of a comprehensive evaluation strategy is the critical role of process evaluation in establishing the overall evaluation's validity and consequently in the interpretation of its findings. If process is not studied in detail, the probability that Type II errors will be committed in the evaluation of effectiveness is raised. That is, without process evaluation, the likelihood that an evaluation of effectiveness will conclude falsely that an intervention is not effective is increased.

Why is this so? The fact that a participant in a field study is assigned to a group that is supposed to receive a specific level of treatment does not assure that he or she actually receives that level of treatment. As a result of factors ranging from participant nonadherence to failure of program staff to follow the protocol, participants in field studies may get more or less intervention than the study design implies. If the actual application of intervention is not measured in some way--in *both* groups--the analyst has no way of knowing whether a lack of difference in outcome between intervention and comparison groups is due to lack of efficacy of the intervention or a failure actually to apply the intervention to the experimental group (and *not* apply it to the comparison group).

Poorly implemented, poorly documented, or poorly understood treatment regimens are perhaps among the most common reasons for misinterpretation of the results of field studies. Consequently, many evaluation methodologists now emphasize the importance of measuring the actual intervention received by each participant in terms of its *timing, duration, intensity, content, and context.*

One of the most interesting--and counterintuitive--results of increased attention to the measurement of "dose" has been recognition of the fact that the "comparison" group frequently gets substantially more treatment than the evaluators intended! Such findings underline the evaluator's relatively limited control in field studies, and demonstrate the importance of measuring carefully the dose of comparison as well as experimental intervention. Thus, measurement of actual intervention dose, in both the experimental and control conditions, is essential to maintaining the validity of the evaluation and for appropriate interpretation of its findings. It also has the added benefit of improving statistical power, and is useful in assessing a variety of other threats to validity, such as treatment contamination and compensatory rivalry. Additionally, the process evaluation will produce valuable information that will itself be useful to the substance abuse prevention field. Consequently, it is important that the WMC program conduct a process evaluation consistent with the program's goals.

B. Proposed Process Evaluation Questions

So, what should the process evaluation be? As usual, we emphasize that design flows from the questions that we are trying to address. Therefore, we provide the following as a straw-person set of questions that we think the process evaluation should answer:

- What are the interventions being tested?
- What is their underlying logic (i.e., how are they *supposed* to work)?
- How were they implemented?
- What is the context in which they were implemented, and did the context change in any meaningful ways over the course of the study?
- What lessons were learned in implementing the interventions that would be helpful to others trying to implement workplace prevention programs?
- To what extent did study participants actually receive an intervention?
- Was it the type and amount of intervention intended by the design?
- What, if any, interventions unintended by the design did participants also receive?
- What changes occurred in participants cognitions or behaviors during the study period that may *mediate* the interventions' intended outcomes?

The first five questions focus on describing the interventions and why, how, and in what context they were implemented. This is information that is available now, and that could be packaged into one or more manuscripts that would be very valuable to the field. As we have previously indicated, we believe that *development of this information should be a high priority for the WMC collaborators now*.

The remaining questions relate to the measurement of dose, and generate information that is useful in analyzing the outcome data. These will be critical to the ultimate understanding and interpretation of the cross-site outcome findings, whatever they turn out to be. We recognize that these questions are designed to serve the cross-site study. Each of the local studies may have other questions that are critical to their local studies, and each site should be planning how to answer those (idiosyncratic) questions as well.

With respect to the cross-site, however, we think that the Measures Subcommittee should: (1) come to agreement on a set of questions for the cross-site process evaluation, (2) recommend methods that produce information that will answer those questions adequately, and (3) formulate both as recommendations to the Steering Committee for adoption by the WMC. We are ready to participate in the process in whatever way the Measures Subcommittee thinks would be helpful.

II. Describe the interventions and why, how, and in what context they were implemented

Content

- Type
- Logic
- Mechanisms
- Motivation
- Measurement Strategies

Organizational Context

- Circumstances
- Contextual Changes
  - organizational
  - MCO
  - -delivery system changes
- Unintended influences
- Costs of the Program
- Estimates of the effects on employees and corporate culture of circumstances and contextual changes (and on covered lives)
- Costs of the program

Schedule of Interventions

- Time line of interventions
- Relationship of implementation factors (timing, target audience, etc.) To intended outcome

II. Measure dose (i.e., intensity and duration of the intervention)

Intervention Intensity and Duration

- Length of individual intervention
  - period of time over which interventions were implemented
- Extent of Intervention
  - proportions of target populations reached by intervention
- Exposure of target population to interventions
- Exposure (leakage) of comparison/control population
  - direct and indirect exposure
- Actual versus intended dos

III. Identify lessons learned that can inform replication efforts

Lessons Learned

- Target Audiences to be informed
  - policy makers
  - purchasers
  - MCO's
  - Service Providers
    -contracted special services
  - Researchers
  - Generic public
  - Other special interest groups
    - benefit advisors
    - media
  - Intervention site
    - participating company
- Helpful strategies
- Recommended changes
- Strengths and weakness - and why

APPENDIX C

Workplace Managed Care

Worksite Survey

Draft 3: 06398

INSTRUCTIONS FOR COMPLETING THIS QUESTIONNAIRE

- Most of the questions in this survey give you a choice of answers. Please read all the answers before marking your choice. If none of the printed answers exactly applies to you, mark the one that most closely applies.

- Please completely erase (or cross-out) any answer you wish to change.

- Some questions will ask you to specify an answer. Please write your response on the line directly after the word (SPECIFY).

  EXAMPLE: How do you get to and from work?

  Car . . . . . ☐

  Truck . . . . . ☐

  Motorcycle . . . . . ☐

  Bus . . . . . ☐

  Other (SPECIFY)_____ . . . . . ☐

- Some questions will ask you to write in a response in the blank provided. Please write in the answer or response that best answers the question.

NOW, PLEASE GO TO THE NEXT PAGE AND BEGIN WITH QUESTION 1.

DRINKING EXPERIENCES

The following set of questions are about drinking alcoholic beverages. By a "drink," we mean a can or bottle, or glass of BEER, a glass of WINE, or a WINE COOLER, a shot glass or a mixed drink with HARD LIQUOR. These questions refer to the use of alcohol for other than religious purposes.

1. In the ***past 12 months***, have you had a drink?

   Yes . . . . . ☐

   No (If no, skip to Question #?) . . . . . ☐

2. During the ***past 30 days***, on how many different days did you have a drink?

   Write in number of days: _____

3. During the ***past 30 days***, on the days that you drank, about how many drinks did you usually have?

   Write in number of drinks: _____

4. Were your drinking practices, ***during the past 30 days***, ***more, less*** or ***about the same***, as your typical pattern?

   More . . . . . ☐

   Less . . . . . ☐

   About the same . . . . . ☐

5. During the ***past 30 days***, on how many days did you have 5 or more drinks on the same occasion? By occasion, we mean at the same time or within a couple of hours of each other.

   Write in number of days: _____

5a. Is this amount ***more, less*** or ***about the same***, as you typically have?

More . . . . . ☐

Less . . . . . ☐

About the same . . . . . ☐

6. Has a doctor, friend, or family member ever asked you to cut down on your drinking?

Yes . . . . . ☐

No . . . . . ☐

RISKS OF ALCOHOL AND DRUG USE

Check the appropriate box to show how much you think people risk harming themselves physically and in other ways when they do the following:

		No Risk	**Slight Risk**	**Moderate Risk**	**Great Risk**
7.	Have 1 or 2 drinks nearly every day	☐	☐	☐	☐
8.	Have 3 or 4 drinks nearly every day.	☐	☐	☐	☐
9.	Have 5 or more drinks nearly every day.	☐	☐	☐	☐
10.	Have 5 or more drinks once or twice a week.	☐	☐	☐	☐
11.	Occasionally smoke marijuana.	☐	☐	☐	☐
12.	Use marijuana on a regular basis.	☐	☐	☐	☐

13. Use cocaine occasionally. . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . . ☐

14. Use cocaine regularly. . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . . ☐

15. Occasionally use prescribed drugs in greater amounts than prescribed. . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . . ☐

16. Regularly use prescribed drugs in greater amounts than prescribed. . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . . ☐

17. Combine alcohol with prescription drugs when cautioned not to do so. . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . . ☐

DRUG USE EXPERIENCE

The following set of questions are about the use of illegal drugs. By "illegal drugs" we mean MARIJUANA, COCAINE (or crack), HEROIN, INHALANTS, HALLUCINOGENS (such as LSD,PCP or mescalline) or the use of legal drugs such as ANALGESICS (e.g., codeine, Percodan, Tylenol w/codeine, Demoral, Darvon), TRANQUILIZERS (e.g., Valium, Xanax, Librium, Avitan, Dalmane, Halcion), STIMULANTS (e.g., methamphetamine, Dexedrine, Ritalin, Fastin, Adipex), SEDATIVES (e.g., barbiturates, phenobarbital, Nembutal, Bendryl, Seconal), ANTI-DEPESSANTS (e.g., Prozac, Paxil, Zoloft, Elavil, amoxapine) used for non-medical purposes or used in ways other than prescribed by a physician.

18. Have you ever used any illegal drugs in ***your lifetime***?

Yes . . . . . ☐

No . . . . . ☐

19. Have you ever used any illegal drugs in ***the past year***?

Yes . . . . . ☐

No . . . . . ☐

20. Have you ever used any illegal drugs in ***the past 30 days***?

Yes . . . . . ☐

No . . . . . ☐

DRUG USE CHECKLIST(OPTIONAL)

This section asks about the use of drugs that are commonly prescribed by a doctor. Please indicate whether you have used these medications in the ***past 30 days***, and whether the use was medical, non-medical or both.

"Medical use" refers to use that is consistent with your doctor's recommendations and/or prescribed instructions.

"Non-medical use" refers to use that is without a doctor's prescription, in greater amounts than prescribed, or more often than prescribed.

DRUG	**Medical use only**	**Non-medical use only**	**Both medical & non-medical use**	**Have not used**
21. Analgesics (e.g., codeine, Percodan, Tylenol w/codeine, Demoral, Darvon)	☐	☐	☐	☐
22. Tranquilizers (e.g., Valium, Xanax, Librium, Ativan, Dalmane, Halcion)	☐	☐	☐	☐
23. Stimulants (e.g., methamphetamine, Dexedrine, Ritalin, Fastin, Adipex)	☐	☐	☐	☐

24. Sedatives . . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . . ☐

(e.g., barbiturates,

phenobarbital, Nembutal,

Benadryl, Seconal)

25. Anti-depressants . . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . . ☐

(e.g., Prozac, Paxil, Zoloft,

Elavil, amoxapine)

26. Other (SPECIFY) _____ . . . . . ☐

_____ . . . . . ☐

_____ . . . . . ☐

_____ . . . . . ☐

DRUG USE FREQUENCY CHECKLIST(OPTIONAL)

The following lists several different kinds of mood-altering drugs. Please check the box according to how many times you have used the drug for medical or non-medical purposes.

If you have not used any of these drugs in the ***past 30 days***, skip this page and proceed to the next section on "Views on Health, Drinking and Drug Use".

*Please check the box according to how many times you have used the following drugs during the **past 30 days:***

		FREQUENCY OF USE					
DRUG		**Not At <u>All</u>**	**Once or <u>Twice</u>**	**A Few <u>Times</u>**	**1 or 2 Times <u>a</u> <u>Week</u>**	**Almost <u>Daily</u>**	**<u>Daily</u>**
27.	Analgesics . . . . . (e.g., codeine, Percodan, Tylenol w/codeine, Demoral, Darvon)	☐	☐	☐	☐	☐	☐
28.	Tranquilizers . . . . . (e.g., Valium, Xanax, Librium, Ativan, Dalmane, Halcion)	☐	☐	☐	☐	☐	☐

29. Stimulants . . . . . ☐ . . . . ☐ . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . ☐
(e.g., methamphetamine, Dexedrine,
Ritalin, Fastin, Adipex)

30. Sedatives . . . . . ☐ . . . . ☐ . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . ☐
(e.g., barbiturates, phenobarbital,
Nembutal, Benadryl, Seconal)

31. Anti-depressants . . . . . ☐ . . . . ☐ . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . ☐
(e.g., Prozac, Paxil, Zoloft,
Elavil, amoxapine)

32. Marijuana . . . . . ☐ . . . . ☐ . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . ☐

33. Cocaine ☐ . . . . . ☐ . . . . ☐ . . . . ☐ . . . . . ☐ . . . . . ☐

34. Heroin . . . . . ☐ . . . . ☐ . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . ☐

35. Hallucinogens . . . . . ☐ . . . . ☐ . . . . ☐ . . . . . ☐ . . . . . ☐ . . . . ☐

36. Other (SPECIFY) _____ . . . . . ☐
_____ . . . . . ☐
_____ . . . . . ☐
_____ . . . . . ☐

EAP/EFAP (other prevention program name) SERVICES

The next set of questions concern your EAP/EFAP (other prevention program name) services. Fill in the square that best fits your response to the questions.

37. Are you aware that an Employee Assistance Program (EAP) is available through your workplace to help you with both personal and work-related problems?

Yes . . . . . ☐

No (If no, skip to question 40) . . . . . ☐

38. Would you use your EAP for a personal or work-related problem?

Yes . . . . . ☐

No . . . . . ☐

Not sure . . . . . ☐

39. Have you ever used your EAP for a personal or work-related problem?

Yes . . . . . ☐

No (If no, skip to question 40) . . . . . ☐

39a. How satisfied are you with the help you received from your EAP?

Very satisfied . . . . . ☐

Somewhat satisfied . . . . . ☐

Neither satisfied nor dissatisfied . . . . ☐

Somewhat dissatisfied ☐

Very dissatisfied . . . . . ☐

GENERAL INFORMATION

Please mark (place an "x" in) the correct box or write in the requested information.

40. Your age? ___

41. Sex:

Male ☐

Female ☐

42. Race/Origin:

White . . . . . ☐

African-American . . . . . ☐

Asian/Pacific Islander . . . . . ☐

Hispanic/Latino . . . . . ☐

Native American . . . . . ☐

Other (SPECIFY)_____ . . . ☐

43. Current marital status:

Single . . . . . ☐

Married . . . . . ☐

Divorced . . . . . ☐

Other (explain) _____ . . ☐

44. Schooling Completed (one choice only): .

Less than high school graduation

or GED . . . . . ☐

High school graduation . . . . . ☐

Some college . . . . . ☐

A bachelors degree or higher . . . . . ☐

45.. Are you a Supervisor/Manager?

Yes . . . . . ☐

No . . . . . ☐

46. What type of job do you have in this organization?

Management/professional (managers, engineers, accountants, teachers) . . . . . ☐

Technical support (plumber, millwright, electrician) . . . . . ☐

Sales . . . . . ☐

Administrative support (clerical, secretarial, data processor, telephone operator) . . . . . ☐

Service (security guards, food service, nursing aide, janitor) . . . . . ☐

Production, construction, operations (mechanics, carpenters, machine operators . . . . . ☐

Transportation (motor vehicle operators, moving equipment operators) . . . . . ☐

Other (SPECIFY) _____ . . . . . ☐

APPENDIX D

Research Triangle Institute (RTI)

Statement of Confidentiality Assurance

As part of the research protocol for the CSAP Workplace Managed Care (WMC) Program, the Research Triangle Institute (RTI) will be receiving data from the participating study sites to conduct the cross-site evaluation. Sites will transfer data defined in the Program's core data set to RTI by transferring files to WMC server, which is firewall and password protected. The data will include information from worksite records, worksite surveys, EAP records, and health care utilization records.

For purposes of the cross-site evaluation, individual level data will be provided by the sites, and merged across databases within a given study site. All data made available to RTI for the WMC study, however, will be stripped by the site evaluation team of any identifying information before they are transferred to the firewall protected WMC server. RTI will obtain the WMC data using a file transfer protocol within the protected firewall, and will merge data across databases using a non-identifying cross-site ID number assigned to each participant by each local evaluation team. Each site will create and manage the 'link file" that matches specific employees with a cross-site ID number. At no point will RTI have access to this link file.

All data acquired during the course of the study by RTI will be kept strictly confidential and shall not be divulged to any person(s), corporations(s), or entity(ies) without the prior knowledge and consent of the WMC Steering Committee. Access to WMC data by RTI staff will be limited to those persons directly involved with the WMC project and only for purposes of the cross-site evaluation. All data associated with this study will be maintained in a secure, dedicated, password protected workstation. Only the assigned WMC analyst(s) will have access to this station. When the data are not being used, they will be removed from the hard drive and kept on CD-ROM (or diskette), in a locked file cabinet.

Consistent with the publication guidelines agreed upon by the WMC Steering Committee, all original data will be kept by RTI for at least 10 years beyond the end of the WMC Program. RTI will not publish or disseminate in any way research findings associated with the WMC Program without prior approval of the WMC Steering Committee. Further, RTI may utilize these data only to disseminate research findings associated with this study in collaboration with the Steering Committee (in aggregate form and without identifying information), within the WMC publication guidelines, and in accordance with 42,CFR, Part 2.